

Remarks

A. Pending Claims

Claims 1019, 1021, 1022, 1023, 1029, 1031, 1033, 1035-1037, 1039, 1041-1043, 1049, 1051, 1053, and 1055-1057 are pending in the application. Claims 1020, 1024-1028, 1030, 1032, 1034, 1038, 1040, 1044-1048, 1050, 1052, 1054, and 1058 have been cancelled. Claims 1019, 1021, 1022, 1023, 1029, 1031, 1033, 1035-1037, 1039, 1041-1043, 1049, 1051, 1053, and 1055-1057 have been amended.

B. Priority

The Office Action states:

This application claims priority to Con 10/629,538 filed 07/29/03, which claims benefit of 60/366,194 filed 07/29/02, 60/467,973 filed 05/05/03, 60/472,831 filed 05/22/03, 60/473,741 filed 05/28/03, 60/485,304 filed 07/03/03.

Applicant respectfully notes that the present application does not claim priority to Patent Application No. 10/629,538, rather, the present application is Patent Application No. 10/629,538. In addition, the present application does not claim priority to Provisional Patent Application No. 60/366,194, however the present application does claim priority to Provisional Patent Application No. 60/399,194. Applicant's specification discloses:

This application claims priority to Provisional Patent Application No. 60/399,194 entitled "Structural Carotenoid Analogs for the Inhibition and Amelioration of Reperfusion Injury" filed on July 29, 2002; Provisional Patent Application No. 60/467,973 entitled "Structural Carotenoid Analogs for the Inhibition and Amelioration of Disease" filed on May 5, 2003; Provisional Patent Application No. 60/472,831 entitled "Structural Carotenoid Analogs for the Inhibition and Amelioration of Disease" filed on May 22, 2003; Provisional Patent Application No. 60/473,741 entitled "Structural Carotenoid Analogs for the Inhibition and Amelioration of Disease" filed on May 28, 2003; and Provisional Patent

Application No. 60/485,304 entitled "Structural Carotenoid Analogs for the Inhibition and Amelioration of Disease" filed on July 3, 2003. (Specification, page 1, lines 4-13).

Applicant respectfully requests the priority claim be amended for the record.

C. The Claims Are Definite Pursuant To 35 U.S.C. § 112 First Paragraph

The Office Action includes a rejection of claims 1019-1058 under 35 U.S.C. 112 First Paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully disagrees with these rejections.

The Office Action states:

Further in the Specification, on page 22, lines 9-19, Applicants indicate that Carotenoids are as many as 600 in number, have been found in human tissue. However, the prior arts do not describe all carotenoid derivatives of the instant compound.

Applicant is unsure of exactly how this statement is relevant to the claimed invention of the present application and so cannot at this time comment on this statement.

The Office Action states:

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support for the broad use of carotenoids that are derivatives of naturally occurring carotenoid, of the instant compounds.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Applicant respectfully submits that the present application claims no uses or “pharmacological activity” and is unclear as to the relevance of the above statement as regards the claimed invention. As far as the Office Actions reference to Genentech Inc. v. Novo Nordisk, Applicant submits the specification does adequately enable the claimed invention as can be found at least in the specification on page 68, line 9 through page 70, line 5.

The Office Action states:

The nature of pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

Applicant respectfully disagrees, additionally Applicant respectfully submits that the present application claims no “therapeutic regimen” and is unclear as to the relevance of the above statement as regards the claimed invention.

The Office Action states:

The term derivative may encompass a great number of compounds related to carotenoids, however, without some guidance as to what changes may be made to the carotenoid, there would be little predictability in making and or using such “derivatives of naturally occurring carotenoids”. For example there is no guidance as to what modifications may be to specific naturally occurring carotenoids to obtain a derivative.

One skilled in the art would not expect any modifications of a naturally occurring carotenoid.

Applicant respectfully submits that the present application claims no uses of derivatives of naturally occurring carotenoids. In addition, Applicant's specification provides numerous examples of how to make derivatives of naturally occurring carotenoids. Applicant respectfully submits that the claims are supported in the specification at least on page 68, line 9 through page 70, line 5.

The Office Action states:

Applicant provides limited working examples of how the instant compound is used in Table 1 page 105 of the Specification. However, the limited examples do not provide sufficient evidence to support a claim drawn to a method for treating heart disease, such as CAD and CAV. Applicant provides no working examples of a carotenoid derivative as a derivative of naturally occurring derivatives, of the instant compound.

Applicant respectfully submits that the present application claims no "method for treating heart disease" and is unclear as to the relevance of the above statement as regards the claimed invention.

The Office Action states:

Claims 1022, 1023, 1024, 1025, 1026, 1027, 1028 and 1042, 1044, 1045, 1046 and 1047 are extremely broad due to the large number of carotenoid derivatives. Applicant has not provided sufficient evidence to support a claim drawn to carotenoid derivative as a derivative of a naturally occurring carotenoid, of the instant compound.

Applicant respectfully submits that the present application claims no uses of derivative of naturally occurring carotenoids. In addition, Applicant's specification provides numerous examples of how to make derivatives of naturally occurring carotenoids.

Applicant respectfully submits that the claims are supported in the specification at least on page 68, line 9 through page 70, line 5.

The Office Action further states:

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

In view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test how the instant compound is useful in treating a heart disease with no assurance of success. Further the specification fails to provide sufficient support of the broad use of the term derivative. As a result necessitating one of skill in the art to perform an exhaustive search for which derivatives can be prepared

Applicant respectfully submits that the present application makes no claims directed towards “treating a heart disease” and is unclear as to the relevance of the above statement as regards the claimed invention.

D. The Claims Are Definite Pursuant To 35 U.S.C. § 112 Second Paragraph

The Office Action includes a rejection of claims 1019, 1039, 1034, 1022, 1042, and 1054 under 35 U.S.C. 112 Second Paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully disagrees with these rejections.

The Office Action states:

In claims 1019 and 1039 the word “comprising” is used. This term is open-ended language. The term is best suited for a composition claim. In the instant case, claims 1019 and 1039 are compound claims. Examiner

suggests applicant replace the term “comprising” with “consisting of”, if applicant intends this claim as a compound claim.

Applicant respectfully disagrees with these rejections, however, in order to expedite prosecution of the present application Applicant has amended claims 1019 and 1039 for clarification. Support for the amendments to the claims may be found, for example, in the specification on page 59, lines 16-28.

The Office Action further states:

Claim 1034 and 1054 state where in the compound is a part of a composition. This claim does not state which part of the compound is a composition with a formula and/or a structure. Further, it is not clear whether this claim is intended as a compound claim or a composition claim. This instant claim appears to be a compound claim because a composition claim should have a carrier.

Applicant respectfully disagrees with these rejections, however, in order to expedite prosecution of the present application Applicant has amended claims 1019 and 1039 for clarification.

The Office Action further states:

In claim 1019 and 1039 the formula of the derivative was claimed, however in claim 1022 and 1042 applicant states that the “carotenoid derivative is a derivative”, however there is no formula associated with the second derivative of the naturally occurring carotenoid. Examiner suggests inserting the formula of all derivatives in present and future claims where pertinent.

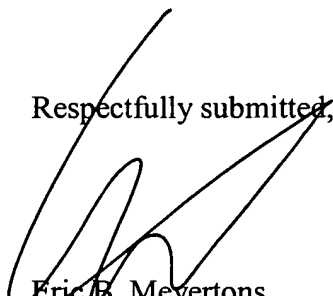
Applicant respectfully disagrees with these rejections, however, in order to expedite prosecution of the present application Applicant has amended claims 1022 and 1042.

E. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

A fee authorization form is included to cover an information disclosure statement. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any additional fees are required or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5777-00201/EBM.

Respectfully submitted,



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